

21 NCAC 46 .2704 REQ FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

- (a) The permit to operate a pharmacy providing radiopharmaceutical services shall be issued by the Board only to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy related to radiopharmaceutical services and shall be in personal attendance at all times that the pharmacy renders radiopharmaceutical services.
- (b) In emergency situations, and in the absence of a qualified nuclear pharmacist, designated qualified licensed professionals as identified by the pharmacist-manager in established written policies and procedures may have access to the area designated as the nuclear pharmacy area, and these individuals may prepare single doses of radiopharmaceuticals for the immediate emergency only and must document such activities.
- (c) The nuclear pharmacy area shall be secured from entry by unauthorized personnel as identified by the pharmacist-manager in established written policies and procedures.
- (d) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radiopharmaceuticals in accordance with Section .2300 of this Chapter and the applicable regulations of the North Carolina Division of Radiation Protection.
- (e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area that provides sufficient protection from radioactivity of all areas surrounding the nuclear pharmacy area. Floor plans shall be submitted and approved by the Board staff before a nuclear pharmacy permit is issued.
- (f) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.
- (g) The library of a nuclear pharmacy shall contain, in addition to the volumes required by Rule .1601(a)(3) of this Chapter, copies of current state and federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.
- (h) All pharmacies performing Radiopharmaceutical Services shall have in effect a procedures manual setting forth the procedures and policies of the pharmacy regarding Radiopharmaceutical Quality Assurance. This manual shall at all times be readily available for review by Board personnel.
- (i) Permit holders must obtain licensure from the North Carolina Division of Radiation Protection and the number of that license. Copies of the Division's inspection report shall be made available upon request for inspection by Board personnel.

*History Note: Authority G.S. 90-85.6; 90-85.34;
Eff. October 1, 1990;
Amended Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.*